

PCT Appl. No. : CT/AU00/00652
Filed : Herewith

28. (New) The device of Claim 25, wherein the actuator is removably attached to the lancet body.

AM
29. (New) The device of Claim 28, wherein the actuator and lancet body are an integral part and the removable attachment of the actuator to the lancet body comprises a pre-formed weakened region disposed between the actuator and the lancet body.

30. (New) The device of Claim 25, wherein the return comprises resilient structure formed in at least one of the lancet housing and the lancet body.

REMARKS

This amendment is being made to bring the subject application into better conformance with U.S. practice, to claim the benefit of previously filed international applications, and to more distinctly claim what the Applicant regards as the invention. No new matter is being introduced. Entrance of the amendment is respectfully requested. Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP.

Dated: 12/10/01

By: James W. Ausley

James W. Ausley
Registration No. 49,076
Agent of Record
620 Newport Center Drive
Sixteenth Floor
Newport Beach, CA 92660
(909) 781-9231

VERSION WITH MARKINGS TO SHOW CHANGES MADE

IN THE ABSTRACT:

[57 Abstract: This invention relates to a disposable lancet device which may be used to pierce human skin sufficiently to let a small quantity of blood for testing. It comprises a lancet housing (12), a lancet body (14) displaceably supported by the housing (12) and having a piercing tip (52) which is concealed within the housing (12) in a rest position of the body (14). It also comprises operating means (46) for manually displacing the lancet body (14) to expose the piercing tip (52). It includes biasing means (36) against which the lancet body (14) operates as it is manually displaced to expose the piercing tip (52), whereby the biasing means (36) automatically retracts the lancet body (14) to its rest position when the manual displacement force is removed from the operating means (46). Disabling the operating means (46) prevents manual displacement of the lancet body (14) from its rest position.]

--Abstract of the Disclosure

A disposable lancet device adapted to pierce human skin sufficiently to let a small quantity of blood for testing. The device includes a lancet housing, a lancet body displaceably supported by the housing, and a piercing tip concealed within the housing in a rest position. The piercing tip can be integral with the lancet body or attached thereto. The device also includes an actuator for manually displacing the lancet body to expose the piercing tip under applied force and a return mechanism that returns the lancet body to the rest position when the manual displacement force is removed from the actuator. The actuator can be disabled to inhibit further manual displacement of the lancet body and exposure of the piercing tip. Thus, the piercing tip can be repeatedly exposed if desired, but can also be disabled once further use is no longer desired.--

PCT Appl. No. : CT/AU00/00652

Filed : Herewith

IN THE SPECIFICATION:

Page 1, immediately after the title, please insert –**Related applications** This application claims the benefit of the Australian application PQ 0892 filed June 10, 1999 and the international application PCT/AU00/00652 filed June 9, 2000.—

IN THE CLAIMS:

Please amend the Claims as follows:

1. (Amended) A disposable lancet device for piercing human skin comprising:
a lancet housing;
a lancet body displaceably supported by the housing and having a piercing tip which is concealed within the housing in a rest position of the body;
[operating means] **an operator** engaged with the lancet body for manually displacing the lancet body to expose the piercing tip; and
[biasing means] **a return** against which the lancet body operates as it is manually displaced to expose the piercing tip whereby the [biasing means] **return** automatically retracts the lancet body to its rest position when the manual displacement force is removed from the [operating means] **operator** wherein the [operating means] **operator** is adapted to be disengaged from the lancet body after use to prevent subsequent manual displacement of the lancet body from its rest position.
2. (Amended) [A] **The** disposable lancet device [according to] **of** claim 1, wherein manual force applied to the [operating means] operator is translated to the lancet body for displacing the lancet body from its rest position.
3. (Amended) [A] **The** disposable lancet device [according to] **of** claim 1, wherein the [biasing means] **return** holds the lancet body in its rest position.
4. (Amended) [A] **The** disposable lancet device [according to] **of** claim 1, wherein the [biasing means] **return** comprises at least one resilient projection extending from the lancet body, wherein the resilient projection is deformed by a portion of the housing when the lancet body is displaced from its rest position.
5. (Amended) [A] **The** disposable lancet device [according to] **of** claim 1, wherein the [biasing means] **return** comprises at least one resilient projection extending from the housing, wherein the resilient projection is deformed by a portion of the lancet body when the

PCT Appl. No. : CT/AU00/00652

Filed : Herewith

lancet body is displaced from its rest position.

6. (Amended) [A] **The** disposable lancet device [according to] **of** claim 1, wherein the [biasing means] **return** comprises a coil spring.

7. (Amended) [A] **The** disposable lancet device [according to] **of** claim 1, wherein the lancet body is supported for linear displacement by the housing.

8. (Amended) [A] **The** disposable lancet device [according to] **of** claim 1, wherein the [operating means] **operator** is disposed on the axis of displacement of the lancet body.

9. (Amended) [A] **The** disposable lancet device [according to] **of** claim 1, wherein the lancet body, operating means and piercing tip form a generally elongate member.

10. (Amended) [A] **The** disposable lancet device [according to] **of** claim 1, wherein the lancet body is non-linearly displaceable.

11. (Amended) [A] **The** disposable lancet device [according to] **of** claim 10, wherein the [operating means] **operator** projects from the housing to one side of the lancet body.

12. (Amended) [A] **The** disposable lancet device [according to] **of** claim 1, wherein the [operating means] **operator** is integrally moulded with the lancet body.

13. (Amended) [A] **The** disposable lancet device [according to] **of** claim 12, wherein the [operating means] **operator** is breakable from the lancet body at a line of weakness at or adjacent the juncture of the lancet body with the housing when the lancet body is in its rest position.

14. (Amended) [A] **The** disposable lancet device [according to] **of** claim 1, wherein the [operating means] **operator** is connected to the lancet body by a connection device.

15. (Amended) [A] **The** disposable lancet device [according to] **of** claim 14, wherein the connection device is a snap engaging connection or screw thread.

16. (Amended) [A] **The** disposable lancet device [according to] **of** claim 1, wherein the piercing tip is secured to the lancet body.

17. (Amended) [A] **The** disposable lancet device [according to] **of** claim 1, wherein the piercing tip is integral with the lancet body.

18. (Amended) [A] **The** disposable lancet device [according to] **of** claim 16, wherein the lancet body is moulded around a mounting portion of the tip.

19. (Amended) [A] **The** disposable lancet device [according to] **of** claim 1,

PCT Appl. No. : CT/AU00/00652

Filed : Herewith

wherein the piercing tip and lancet body are moulded from the same or different plastics material selected from polycarbonate, polystyrene, and polypropylene.

20. (Amended) [A] **The** disposable lancet device [according to] **of** claim 18, wherein the piercing tip is formed of metal [, preferably stainless steel].

21. (Amended) [A] **The** disposable lancet device [according to] **of** claim 1, wherein the piercing tip has a cylindrical body tapering to a pointed end.

22. (Amended) [A] **The** disposable lancet device [according to] **of** claim 1, wherein the piercing tip is multi-sided.

23. (Amended) [A] **The** disposable lancet device [according to] **of** claim 22, wherein the tip is pyramidal or flat with sharp leading edges.